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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,006	06/07/2006	Ching-Juh Lai	NIH272.001NP	8938

45311 7590 02/26/2009  
KNOBBE, MARTENS, OLSON & BEAR, LLP  
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EXAMINER
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MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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02/26/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,006	<b>Applicant(s)</b> LAI ET AL.	
	<b>Examiner</b> Mary E. Mosher	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 and 32-34 is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 24 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/9/06.

### ***Claim Objections***

Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 is drawn to a monoclonal antibody. Since antibodies necessarily comprise Fd and Fab regions, claims 2 and 3 do not further limit the scope of claim 1. Perhaps claim 1 should be amended to recite "antibody or antibody fragment that binds or neutralizes...".

### ***Claim Rejections - 35 USC § 112***

Claims 1-12, 14-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the rejection does not provide reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention, because the reasons given cited a textbook

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that was published at least ten years before the invention. However, applicant has not pointed to any developments in the art of antibody-antigen binding that negate the teachings of the classic textbook, or provide reason to believe that the sequence of the recited CDR3 region alone is sufficient to confer the functionality of binding and/or neutralizing dengue virus type 1, 2, 3, and/or 4.

Applicant points to assertions in the specification that the CDR3 regions, and more particularly the heavy chain region, are largely responsible for antibody specificity, and that applicants contemplated replacement of CDR1, CDR2, and light chain CDR3 regions of 5H2. However, it is noted that, in applicant's disclosure, antibodies 5H2 and 5D9 have the same CDR3 sequence (Fig. 2B), but have different binding behavior. See specification page 11, lines 5-6 and page 34, lines 11-14 (paragraphs 30 and 104 in US 20070134256). It is also noted that applicants themselves, in their peer-reviewed publication, point to differences in the CDR1, CDR2, and other regions of V<sub>L</sub> as possibly explaining differences in binding between these two antibodies with identical CDR3 sequences (see Men et al, Journal of Virology 78:4665-4674, 2004, the paragraph spanning pages 4670-4671). Although both 5D9 and 5H2 do share the same CDR3 sequence and do both bind dengue type 4, these two provide evidence that structure of the CDR3 region alone does not control the function of the antibody. Therefore, it is maintained that the specification does not reasonably convey possession of the genus of antibodies that bind or neutralize dengue virus comprising only the CDR3 region of SEQ ID NO:7.

***Response to Amendment***

In response to the amendment filed 12/18/2008, the rejections under 35 USC 112, second paragraph, 35 USC 102, and 35 USC 103 are withdrawn.

***Allowable Subject Matter***

Claims 23, 32-34 are allowed. Claim 13 would be allowable if limited to the elected species.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is 571-272-

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0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/  
Primary Examiner, Art Unit 1648

2/19/09